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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,793	04/14/2004	James J. Modliszewski	60310-USA	6666

7590 11/01/2006

Paul A. Fair - Patent Administration
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EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,793	MODLISZEWSKI ET AL.	
	Examiner	Art Unit	
	Everett White	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants response filed August 11, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Comments regarding Office Action have been provided drawn to:
- (I) nonstatutory double patenting rejection, which is maintained for the reasons or record;
- (II) 103(a) rejection, which is maintained for the reasons of record.

2. Claims 1-27 are pending in the case.

3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 2 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 44 and 45 of

copending Application No. 10/824,688 for the reasons disclosed on pages 2 and 3 of the Office Action mailed March 6, 2006.

6. The Examiner acknowledges Applicant's request that the nonstatutory obviousness-type double patenting rejection be held until such time as notice of patentable subject matter has been received in the applications. Applicants indicated an appropriate terminal disclaimer will be filed at that time if necessary.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-17, 20, 21 and 23-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376) for the reasons disclosed on pages 4-7 of the Office Action mailed March 6, 2006.

9. Claims 18, 19 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376) for the reasons disclosed on pages 7-9 of the Office Action mailed March 6, 2006.

Response to Arguments

10. Applicant's arguments filed August 11, 2006 have been fully considered but they are not persuasive. Applicants appear to argue against the rejection on the ground that the structurally differences between the kappa-2 carrageenan disclosed in the delivery composition of the instant claims and the kappa-carrageenan or iota-carrageenan disclosed in the delivery composition of the Gennadios patent is sufficient to over come the 103 rejection of the instant claims over the Gennadios patent. This argument is not persuasive because kappa-2 carrageenan and kappa carrageenan or iota carrageenan do possess common characteristics, structurally and properties, as pointed out in the instant specification (see pages 4-7). Applicants have not show that the composition of the Gennadios patent comprising kappa carrageenan and iota carrageenan is different in a non-obvious minor from the composition of the instant claims comprising kappa-2 carrageenan. Where the claimed and prior art compounds possess a close structural relationship and a specific significant property in common which renders the claimed compounds obvious to one skilled in the art, they are effectively placed in the public domain and unpatentable per se, even though the Applicant has discovered that they possess an additional activity. In re Mod et al. (CCPA 1969) 408 F2d 1055, 161 USPQ 281 ; Monsanto Co. v. Rohm & Haas Co. (DC Pen 1970) 420 Fsupp 950, 164 USPQ 556 (affd. On other grounds, 172 USPQ 323).

Applicant also argues that the Gennadios patent provides no disclosure or suggestion of incorporating an active substance in the gel film itself. This argument is not persuasive since the Gennadios patent does disclose a list of materials (see column 5, lines 9-15) that may be added to the composition thereof which embraces some of the active substances disclosed in instant Claims 2 and 19. Accordingly, the rejection of

Claims 1-27 under 35 U.S.C. 103(a) as being unpatentable over the Gennadios patent is maintained for the reasons of record.

Summary

11. All the claims are rejected.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

E. White

E. White

10/19/06

Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600